

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING )  
PHARMACY, INC. PRODUCTS LIABILITY )  
LITIGATION )  
\_\_\_\_\_  
THIS DOCUMENT RELATES TO: )  
 )  
ALL CASES )  
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 )  
MDL No. 2419  
Dkt. No 1:13-md-2419 (RWZ)

**SAINT THOMAS ENTITIES' REPLY BRIEF IN SUPPORT OF THEIR MOTION TO  
COMPEL INVOKING DEFENDANTS TO PRODUCE CERTAIN DOCUMENTS**

Neither the United States (“United States” or “Government”), Barry Cadden, Glenn Chin, Gregory Conigliaro, Douglas Conigliaro, nor Carla Conigliaro (the “Invoking Defendants”) provide any legitimate grounds for this Court—which is also presiding over discovery matters in the related criminal trial—to preclude the Saint Thomas Entities from obtaining the discovery they need to defend themselves in the multidistrict litigation (“MDL”). This litigation exists solely because of the conduct of Cadden and his cohorts, the owners, managers, and supervisors of New England Compounding Center (“NECC”). They should be compelled to produce the documents requested because:

- The evidence in question is highly relevant to the NECC MDL, and neither the Invoking Defendants nor the Government can legitimately argue to the contrary;
- The Invoking Defendants are the sole persons in the MDL with possession, custody, and control of most, if not all, of the relevant evidence at issue;
- The Saint Thomas Entities are not seeking secret grand jury materials, making the case law and procedures the Invoking Defendants cite irrelevant;
- The Saint Thomas Entities are not seeking extraordinary relief and the burden of production on the Invoking Defendants is minimal; and

- The civil cases cannot possibly go forward before the criminal trial unless the health care defendants are provided equal access to the evidence on NECC's culpability.

**I. The Evidence at Issue is Highly Relevant and Integral to the Saint Thomas Entities' Comparative Fault and Sole Intervening Cause Defenses**

Barry Cadden and his cohorts are solely responsible for the nationwide meningitis outbreak and resulting injuries and deaths at issue in this litigation. Operating as NECC, Cadden and his associates defrauded customers across the country into believing NECC was compounding high quality products that met all United States Pharmacopeia ("USP") requirements and that had been fully tested for sterility. As a result of their actions, the Invoking Defendants are before this Court for two reasons: 1) they were sued across the country for civil liability; and 2) they have been indicted for criminal responsibility.

The same facts and evidence are highly relevant to both proceedings. As just a few examples:

- How did the contamination of methylprednisolone acetate ("MPA") at issue in this litigation occur?
- How was NECC's sales force trained to sell the safety of its products?
- How was the MPA actually compounded?
- How was NECC avoiding regulatory oversight?
- Why did NECC fail to send enough samples to testing labs?
- How long did NECC actually steam sterilize its batches of MPA?
- What was NECC's work flow for compounding MPA?
- What are the circumstances under which NECC disregarded required practices, policies, and procedures?

The Plaintiffs' Steering Committee ("PSC") is trying to hold the Saint Thomas Entities and other health care providers liable for the actions of NECC and its owners and managers. As part of their defense, the health care defendants are entitled to show the jury that NECC is solely responsible for the patients' injuries. If a jury determines a health care provider is also responsible for a patient's injury, the jury will then be required to allocate fault between NECC and that health care provider. As the jury instructions in such situation explain:

In making the apportionment of percentage of fault, you should keep in mind that the *percentage of fault chargeable to a [person] is not to be measured solely by the number of particulars in which a [person] is found to have been at fault.*

[. . .]

You should weigh the respective contributions of the persons, *considering the conduct of each as a whole*, determine whether one made a larger contribution than the other(s), and if so, *to what extent it exceeds that of the other(s).*

The percentage of fault assigned to any person *depends upon all of the circumstances of the case.* The conduct of each person may make that person more or less at fault, *depending upon all of the circumstances.* In order to assist you in making this decision, you may consider the following factor(s) and you may also *consider any other factors that you find to be important under the facts and circumstances.* But the determination of fault on the part of any person and the determination of the relative percentages of fault, if any, are matters for you alone to decide.

1. Whose conduct *more directly caused* the injury to the plaintiff;
2. *How reasonable was the person's conduct* in confronting a risk, for example, did the person know of the risk or should the person have known of it . . . .

See Tennessee Pattern Jury Instructions—CIVIL §§ 3.51 Comparative Fault, Basis of Comparison; 3.52 Additional Factors for Comparing Fault (emphasis added).

In other words, all of the actions of Cadden and his cohorts that led to the contamination are relevant, admissible evidence for the juries in the Tennessee cases to consider in determining what fault NECC bears for plaintiffs' injuries. The Saint Thomas Entities intend to argue at trial that percentage is 100%, and they must have the evidence to support that argument. And to the

extent the jury holds more than NECC responsible, the evidence at issue will help establish how the contamination occurred and thus who should be allocated fault for causing or contributing to it (such as Liberty Industries, Inc., UniFirst Corporation a/d/b/a UniClean Cleanroom Services, and Ameridose LLC).

This same evidence of the extent of responsibility, or “all of the circumstances of the case,” is the same type of evidence that will determine whether the Invoking Defendants are also held criminally responsible. If they are, this same evidence will determine for which crimes (e.g., whether their actions were negligent, reckless, or intentional) and the extent of punishment (i.e., how much jail time should they serve?). As the federal sentencing guidelines explain, relevant conduct for sentencing includes “all acts and omissions committed” and “all harm that resulted.” *See* 2014 Guidelines Manual, § 1B1.3 “Relevant Conduct (Factors that Determine the Guideline Range). In other words, “all” of the circumstances leading to the contamination of the MPA and resulting injuries and deaths are relevant to the criminal action, and consequently, the civil cases arising out of the Invoking Defendants’ conduct.

## **II. The Protective Order in the Criminal Case is No Barrier to Production Here**

First, discovery in the MDL and criminal cases are both proceeding before Judge Boal. To the extent the protective order entered in the criminal case needs to be amended to clarify that the evidence may also be used in the MDL, it can easily be done. *See, e.g., United States v. Bulger*, 283 F.R.D. 46, 53 (D. Mass. 2012) (stating that the court “undeniably has the discretion and the authority to modify or vacate” a protective order under Rule 16(d) and/or its inherent power to control the discovery process).

Perhaps more importantly, the protective order in the criminal matter is extremely narrow and only covers personal health and financial information. That is why the Saint Thomas

Entities specifically *excluded* patient medical records and prescriptions from their discovery request. And even confidential material may be disclosed to “potential witnesses” in the criminal case.<sup>1</sup> The exact same type of patient information over which the Invoking Defendants feign concern is already subject to production and protection in the MDL pursuant to protective order governing this proceeding. The existence of a protective order governing confidential patient information in the criminal case is no barrier to production under the protective order in the civil case.

### **III. The Right To A Fair Trial Is In No Way Implicated By The Saint Thomas Entities’ Discovery Requests**

The Invoking Defendants attempt to argue that their right to a fair criminal trial would somehow be endangered if they were required to participate in MDL discovery. First, they argue it would be “inordinately expensive and time consuming” to do so. However, they provide no evidence of this fact, on which they bear the burden of proof. *See, e.g., Oppenheimer Fund v. Sanders*, 437 U.S. 340, 358 (1978). Moreover, as explained by the Court in *eBay v. Digital Point Solutions*, such a claim lacks merit when a party offers to take the government’s production *en masse*, which the Saint Thomas Entities have offered to do here. *See eBay, Inc. v. Digital Point Solutions, Inc.*, 2010 U.S. Dist. LEXIS 7997, at \*22 (N.D. Cal. Jan. 12, 2010). The sum total of the “burden” the Invoking Defendants face is to have one of their multiple retained attorneys make a copy of an external hard drive, the costs for which the Saint Thomas Entities will provide reimbursement. Accordingly, no time will be “diverted” from preparing for the April 2016 criminal trial.

Similarly, the claim that the highly relevant, key evidence in the Invoking Defendants’ possession should not be produced because “there are instances where a protective order is

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<sup>1</sup> *See U.S. v. Cadden, et al.*, No. 1:14-cr-10363, Dkt. No. 209, ¶ 4.

violated” is spurious. Under that argument, nobody would ever be required to produce confidential information. Yet attorneys are officers of the Court, and even trade secrets get produced in litigation under protective orders. The Government’s arguments regarding “pre-trial publicity” are likewise groundless given the fact a protective order already exists in the MDL. And tellingly, none of the parties opposing the document production can point to one instance where this Court’s protective order has been violated in the many months since this MDL has commenced.

#### **IV. The Saint Thomas Entities Are Not Seeking The Production Of Grand Jury Materials**

The Saint Thomas Entities have not asked for grand jury materials and do not care what was, or was not, presented to the grand jury. First, the Saint Thomas Entities sent the Invoking Defendants document requests categorizing exactly what documents they were seeking. The Invoking Defendants responded by invoking the Fifth Amendment and refusing to produce anything. Accordingly, because materials in the government’s possession do not implicate the Fifth Amendment, the Saint Thomas Entities revised their request and simply asked for the materials the government had provided them, many of which were seized during the government’s raid of NECC’s premises.

What the government has given the Invoking Defendants are the required disclosures of Federal Rule of Criminal Procedure 16, which states:

(E) *Documents and Objects.* Upon a defendant’s request, the government must permit the defendant to inspect and to copy or photograph books, papers, documents, data, photographs, tangible objects, buildings or places, or copies or portions of any of these items, if the item is within the government’s possession, custody, or control and:

- (i) the item is *material to preparing the defense*;
- (ii) the government *intends to use the item* in its case-in-chief at trial; or

(iii) the item was *obtained from or belongs to the defendant*.

FED. R. CRIM. P. 16 (emphasis added). Importantly, the government is not required to disclose materials presented to a grand jury *even to the criminal defendant* except in very limited circumstances, such as where such materials also fall within Rule 16 (e.g., a document was presented to the grand jury and was obtained from or belongs to the defendant). Here, the Government appears to have disclosed some Grand Jury materials pursuant to FED. R. CRIM. P. 6(e)(3)(E)(i), “preliminary to or in connection with a judicial proceeding.” While the Government attempts to use this as a shield to production in the MDL, the fact that this is the basis of the Government’s production to the Invoking Defendants actually supports the Saint Thomas Entities’ request here. This is not a request by a newspaper or random member of the public. This is a request seeking production of the document disclosure provided “in connection with a judicial proceeding”—In particular, for use in the MDL brought by the same victims of NECC that forms the basis of the Government’s prosecution. To the extent the government has voluntarily decided to disclose otherwise secret grand jury materials because of its obligations under Rule 16 or elsewhere, that does not make the Saint Thomas Entities’ request for relevant materials an attempt to obtain “secret” grand jury materials.

The *Diamante* case cited by the Invoking Defendants is of no consequence here. There, civil plaintiffs served a request for production on criminal defendants specifically seeking “all transcripts and exhibits in the possession of [the defendants] or [their] attorneys from grand jury proceedings in the criminal investigation . . . .” *Liberty Mut. Ins. Co. v. Diamante*, 193 F.R.D. 15, 17 (D. Mass. 2000). After the plaintiffs *explicitly* requested production of grand jury materials, the court stated that the request was improper due to lack of notice to the United States Attorney. *Id.* at 18. Here, there was no such explicit request for grand jury materials. To the

extent such materials have been implicated by the discovery request, the U.S. Attorney certainly has been provided notice. Indeed, the U.S. Attorney has moved to intervene and filed an opposition. The matter has been joined and is ripe for decision by this Court.

**V. The Saint Thomas Entities are Entitled to a Fair Trial, and the Invoking Defendants are the Sole Source of This Key Evidence**

When NECC was raided, the Government seized millions of pages of key evidence in both paper and electronic copy. Because those papers were *returned* to the Invoking Defendants in connection with the Government's disclosure obligations, the Invoking Defendants are attempting to use the criminal proceedings as a bar to producing them in this MDL. However, because of the Government raid, the Invoking Defendants are the only persons who can produce the highly relevant materials.

As an example, the Saint Thomas Entities have sought the marketing videos and training materials from MSM (which was owned and operated by Cadden and other criminal defendants). *See* MSM's 2011 Annual Report, attached as Exhibit A. Because MSM is a company, it has no Fifth Amendment privilege and must produce documents. *See Amato v. United States*, 450 F.3d 46, 48 n.2 (1st Cir. 2006) (stating that corporations and collective entities have no Fifth Amendment privilege against self-incrimination); *see also Braswell v. United States*, 487 U.S. 99, 110 (U.S. 1988) (same). However, counsel for MSM has stated that MSM's only source of the seized videos and training materials is the Government's document production. Accordingly, MSM has not produced the videos or training materials. Merely because the government seized MSM's business records *and then gave them back* to MSM's owners in the context of a pre-trial disclosure does not somehow make them no longer subject to discovery in this civil MDL. How MSM trained its sales representatives to hawk NECC's products is highly relevant to the amount of fault both NECC and MSM should be allocated in the Tennessee trials. It is also highly

relevant to the health care providers' defense that they were not negligent in relying on MSM's assurances that NECC product was high quality, safe, and effective.

Moreover, the letters submitted by the Saint Thomas Entities' from the U.S. Attorney demonstrate that the Government's disclosure to the criminal Defendants has been carefully indexed and produced in clearly labeled folders on a hard drive. To the extent this Court concludes certain types of information should not be produced, the material can easily be segregated. However, the Government seized thousands of pages of records from NECC, thereby precluding any other party from possessing them. Those records have now been returned to the criminal defendants. Merely because business records were seized does not make them any more, or any different, from what they were pre-seizure: discoverable business records under federal law.

At the same time the seized evidence is being kept from the health care providers, the key witnesses to NECC's fault in solely causing the meningitis outbreak are refusing to testify, a decision upheld by this Court in granting them protection from a deposition. *See* Dkt. No. 2123. Without the documentary evidence they need and being kept from the depositions they need, the PSC is attempting to rush the Saint Thomas Entities to trial before the criminal trial of the Invoking Defendants. The Saint Thomas Entities are being pushed to designate experts without the key evidence in the Invoking Defendants' possession, including basic information such as the evidence establishing in which cleanroom the MPA at issue was compounded.

If there is any hope of moving the MDL docket forward at the same time as the criminal trial proceeds (a decision many federal courts caution against) without prejudicing the Saint Thomas Entities' right to a fair trial, the highly relevant evidence being held by the Invoking Defendants and their many lawyers must be produced.

## **VI. The Government's Arguments Likewise Lack Merit**

The Government has moved to intervene in the MDL and filed briefing opposing the Saint Thomas Entities' motion to obtain the documents seized from NECC, MSM, Cadden and others. But the Government does little more than raise speculative concerns.

### **A. This is not a Matter of “Public Access,” and FOIA Cases Brought by Newspapers are Irrelevant Here**

The Government first contends this is a “fishing expedition,” and states “the law is clear that there is no public right of access to criminal discovery.” *See* United States’ Motion in Opposition at p. 17. First, notwithstanding the “constitutional presumption of public access to documents submitted in conjunction with criminal proceedings,” it is not “the public” which seeks the documents in question. It is health care providers who have been sued in federal court and from whom Plaintiffs are seeking money judgments for millions of dollars for injuries caused by the acts or omissions of the defendants in the criminal proceeding. Federal law is clear, and Due Process demands, that health care providers be provided a full and fair chance to defend themselves from such allegations. The Federal Rules of Civil Procedure were instituted to assure that Due Process, and the materials in question are undeniably relevant and discoverable under those Rules. *See Bulger*, 283 F.R.D. at 51-52 (citing *In re Providence Journal Company*, 293 F.3d 1, 11 (1st Cir. 2002)).

Next, the cases cited by the Government for its contention that there is no public right of access to criminal discovery are completely irrelevant. All five involve newspaper publishers seeking information from a party and the courts’ analysis of the newspapers’ First Amendment rights in seeking such information. *See Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 37 (U.S. 1984) (newspaper sought disclosure of certain members of an organization as well as donations made to the organization); *In re Boston Herald, Inc.*, 321 F.3d 174, 175-176, 191 (1st Cir. 2003)

(denying a newspaper's intervention to unseal financial documents submitted by a defendant); *Anderson v. Cryovac, Inc.*, 805 F.2d 1, 3 (1st Cir. 1986) (explaining that once the Government granted access to discovery materials to one news media outlet, a court may not "selectively exclude news media from access to information . . . ."); *Bulger*, 283 F.R.D. at 49, 52, 56 (denying newspaper's motion to vacate protective order so it could obtain information on undisclosed informants); *United States v. Salemme*, 985 F. Supp. 193, 194, 196 (D. Mass. 1997) (granting newspaper's request for access to certain submissions by defendant and concluding that "the government has not provided justification for the continued impoundment of defendants' submissions concerning the motion to dismiss or any part of them.")

In short, the United States does not cite a single case with the same factual issues presented here. This is not a Freedom of Information Act request, nor are the Saint Thomas Entities seeking information for public dissemination. Rather, the Saint Thomas Entities seek highly relevant materials that are critical to their defense in almost 100 lawsuits currently pending in this MDL.

**B. There are No Legitimate Grand Jury Concerns Because the Materials Have Been Provided to the Criminal Defendants**

With respect to Grand Jury materials, the Government makes similar arguments to those made by the Invoking Defendants, which were addressed above. The Government has not identified any particular materials it believes warrant protection or explained in any meaningful detail why particular materials should not be shared under a protective order with federal litigants. The Government made the same attempt at blanket, generic assertions in the *Bulger* case. There, defendant and a newspaper sought to lift the government's protective order covering materials it had produced. *Id.*, 283 F.R.D. at 48. The government argued that the production included "highly sensitive documents," including grand jury transcripts, and should

therefore remain protected. *Id.* The court held it was “difficult to fathom” that all of the documents produced were “sensitive, confidential, grand jury testimony, Title III material or otherwise suitable and appropriate for continued protection,” and rejected the blanket assertions. *Id.* It required the government to identify by category and Bates number each document that it contended should remain subject to continued protection, including documents related to grand jury proceedings. *Id.* at 54, 55, and 58.

It is equally “difficult to fathom” here that the millions of pages of documents are appropriate to be withheld from the health care providers in the MDL. The Government has made the same, sweeping, generic objections that it did in the *Bulger* case. This Court should likewise reject such an approach. And because this is not a case of a newspaper seeking public dissemination, the Court can protect the government’s legitimate interest in avoiding pre-trial publicity by ordering the documents produced pursuant to the protective order already in place. Importantly, the materials in question have already been provided to the criminal defendants. The materials are no longer “secret” as they were prior to the indictments being issued. The Government fails to explain how any harm whatsoever could possibly come from equally sharing those documents with the health care providers, who are being sued for the criminal defendants’ creation and distribution of contaminated product.

### **C. The MDL Protective Order Will Keep The Materials Confidential**

Next, the Government echoes the Invoking Defendants’ argument that there is a *possibility* that the information contained in its criminal discovery *could be* leaked. As explained above, that is no basis to preclude production under the protective order already in place that has governed confidential information to date.

**D. The NECC Criminal Prosecution Does Not Implicate Classified Information or The National Security Concerns of the *Moussaoui* Case**

The Government’s proposition that “allowing the St. Thomas Entities to have criminal discovery would set a dangerous precedent for civil litigants in other parallel criminal and civil cases” is also without merit. *See* United States’ Motion in Opposition at pp. 19-20. Indeed, the only “dangerous precedent” that could arise from this situation is if the Saint Thomas Entities’ motion were denied. For then, through the Government’s exercise of the police power of seizure, it will have precluded civil litigants from obtaining key business records that are clearly discoverable under federal law and integral to their defense. Due process for both the criminal and civil cases requires equal access to relevant documents.

In support of their argument, the Government cites—at length—the Fourth Circuit case of *United States v. Moussaoui*, a non-binding and factually distinct decision. 483 F.3d 220 (4th Cir. 2007). There, an appeal arose in the context of the criminal prosecution of Zacarias Moussaoui, a terrorist involved in the September 11 attacks. *Id.* at 223-24. Civil litigants, victims of the September 11 attacks, sought discovery materials the Government had provided to Moussaoui in the criminal case against him. *Id.* These materials implicated ***national security concerns***, as they contained “particularly sensitive discovery materials,” documents “concerning civil aviation security,” and ***classified information***. *Id.* at 224 (emphasis added). Documents concerning the compounding of contaminated drugs hardly warrant the same protection as classified information bearing on the national security of this country.

Similarly, citing *Moussaoui*, the Government suggests that providing civil litigants with non-public criminal discovery might place an “unfair burden” on the Government, because if the government were forced to disclose the requested documents, “it would have good reason to discontinue open door policies because of concerns over increased general access to sensitive

materials.” United States’ Motion in Opposition at p. 20; *Moussaoui*, 483 F.3d at 238. Again, the materials at issue in *Moussaoui* implicated national security concerns, including classified documents. Here, no such materials are at issue; thus, no such alleged burden would be placed on the Government.

The Government also cites *Moussaoui* for its contention that “there is a real question of whether a criminal court is competent to review the necessity for a discovery order with respect to civil litigation in another jurisdiction.” United States’ Motion in Opposition at p. 20; *Moussaoui*, 483 F.3d at 237. Here, the same Magistrate Judge is presiding over discovery matters in both the civil and related criminal trial. As such, the Government’s point is immaterial.

## **CONCLUSION**

Neither the Invoking Defendants nor the Government present any legitimate reasons to prevent the health care providers being sued in the MDL for NECC’s actions from obtaining the highly relevant materials seized from NECC and others. The health care providers need this information in order to establish for civil juries why NECC should be allocated 100% of the fault for the contamination. And to the extent a jury holds more than NECC responsible, the evidence at issue will help establish how the contamination occurred and thus who should be allocated fault for causing or contributing to it (such as Liberty, Ameridose, and UniFirst). For these reasons, the Saint Thomas Entities request an order compelling the Invoking Defendants to produce the documents the government has produced to them other than patient medical records and prescriptions.

SAINT THOMAS WEST HOSPITAL,  
FORMERLY KNOWN AS ST. THOMAS  
HOSPITAL, SAINT THOMAS NETWORK,  
AND SAINT THOMAS HEALTH

By their attorneys,

/s/ Sarah P. Kelly

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Sarah P. Kelly (BBO #664267)

skelly@nutter.com

NUTTER McCLENNEN & FISH LLP

Seaport West

155 Seaport Boulevard

Boston, Massachusetts 02210

(617) 439-2000

(617) 310-9461 (FAX)

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OF COUNSEL:

Yvonne K. Puig\*

yvonne.puig@nortonrosefulbright.com

Texas State Bar No. 16385400

Adam T. Schramek\*

adam.Schramek@nortonrosefulbright.com

Texas State Bar No. 24033045

Eric J. Hoffman\*

eric.hoffman@nortonrosefulbright.com

Texas State Bar No. 24074427

Norton Rose Fulbright US LLP

98 San Jacinto Blvd. Suite 1100

Austin, Texas 78701

(512) 536-2450

(512) 536-4598 (FAX)

Marcy Hogan Greer\*

Texas State Bar No. 08417650

mgreer@adjtlaw.com

ALEXANDER DUBOSE JEFFERSON & TOWNSEND LLP

515 Congress, Suite 2350

Austin, Texas 78701

(512) 482-9300

(512) 482-9303

\*Appearing *Pro Hac Vice*

**CERTIFICATE OF SERVICE**

This certifies that a true and accurate copy of the foregoing was served on all parties of record by virtue of the Court's electronic filing system this 8th day of September, 2015.

*/s/ Sarah P. Kelly*  
SARAH P. KELLY